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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/445,297	12/02/99	VANDECRUYS R	JAB-1282

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EXAMINER	
KULKOSKY,P	
ART UNIT	**PAPER NUMBER**
1615	4

DATE MAILED: 01/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/445,297	Applicant(s) Roger P. G. Vandeerurys
	Examiner – P. Pulkosky	Group Art Unit 1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

P ri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) ~~1 - 15, 20, 21~~ is/are pending in the application.

Of the above claim(s) 21 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) ~~1 - 15, 20~~ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Oth r _____

Office Acti n Summary

Claims 1-15, 20, 21 are subject to restriction under 35 U.S.C. 121 in that they comprise more than one distinct and independent invention.

The inventions are grouped as follows:

I) Claims 1-15, 20 which are drawn to a composition and treatment methods classified in class 424, subclass 464.

II) Claim 21 which is drawn to a packaged composition classified in Class 206, subclass 363.

The inventions are distinct, each from the other because:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a non-packaged dosage form and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Mary Appollina on December 21, 2000 a provisional election was made with traverse to prosecute the invention of I, claims 1-15, 20. Affirmation of this election must be made by applicant in replying to this Office action. Claim 21 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Putteman et al 5,814,330 or EPA 0,689,844 or WO 94/12217.

The pharmaceutical compositions of the instant claims contain cyclodextrin, active agent which is difficultly soluble and polymeric stabilizer. However, these components are well-known to be combined in dosage forms which release difficultly soluble active agent (see working example of EPA 0,689,844 for species such as beta-cyclodextrin, vinpocetine and tartaric acid). The classes of ingredients sparingly water soluble drug, cyclodextrin, water soluble polymer and

water-soluble acid are clearly used together in formulas of the cited Prior Art (see Putteman et al, Cols 6-8). The stabilizing effects of polymers are described in WO 94/12217.

The drug dissolution profiles of the Tables of the specification are noted, but comparison with the closest prior formulas is necessary to demonstrate unexpected results. In any case, the claims do not require specific formulas of the instant specification.

Claim 19 is rejected under 35 U.S.C. 101.

The term "use" is not equivalent to a method or definite process.

Claims 1-15, 20 are rejected under 35 U.S.C. 112, par. 2.

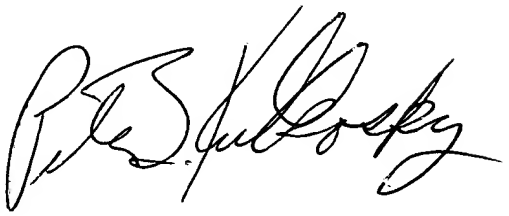
Bioavailability of the release forms described as the invention in the specification is not required as a property for the composition of the claims.

Bioavailability data for certain formulas indicate that this property is necessary to define the compositions which are improved.

Reference (B), (C), (D) are cited of interest.

Kulkosky/LR

January 4, 2001



PETER F. KULKOSKY
PRIMARY EXAMINER